DETAILED ACTION

See interview summary.

Claims 1, 3-7,9-11 and 14-19 are pending.

Election/Restrictions

Applicant's election with traverse of Group 5, wherein C in the formula (I) is H, in the reply filed on 04/17/2008 is acknowledged. The traversal is on the ground(s) that the different inventions are linked by a special technical feature. This is not found persuasive because as properly stated in papers 03/17/2008, the invariant in all the groups are bonds and -CH2-, which are fundamental units in organic compounds. As such these features are not contributions over prior art.

Applicant points out that claims 15-18 of Group 29 are directed to pharmaceutical compositions and not to pharmaceutical methods. Further Group 53 is making of compounds. As such, Group 5, 29 and 53 are linked by a special technical feature. This is not persuasive for above stated reasons. The claims 11, 15-18 are grouped as pharmaceutical methods because of the inclusion of language that combines the compounds of formula (I) and pharmaceutically active additional compounds.

The requirement is still deemed proper and is therefore made FINAL.

Claim 10, 15-19 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/17/2008.

This application contains claim10,15-19 drawn to an invention nonelected with traverse in the reply filed on 04/17/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, 9 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a limited class of compounds of the formula (I), does not reasonably provide enablement for the plurality of general structures claimed. Thus while prior art teaches (see rejections under 35 U.S.C. 102) substituents (R1a)m-A and B-CH2-R1b, the linker unit C of the formula (1) has 5 substituents which have independently varying groups layered with substituents on top of substituents of which, enabling disclosure is found for one possibility, i.e., R2b = F. It is not seen where in the disclosure enablement is present for biological activity for the *elected* group of compounds. As such, the specification does not enable any person skilled in the art to which it pertains, or with which is most nearly connected, to make and use the compounds of the invention commensurate in scope of these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art.

All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

The breadth of claims: The formula (I) encompasses several independently varying groups layered with substituents on top of substituents leading to a large number of conceivable structures of widely different physical and chemical properties, characteristics that are art recognized to have major impact on the PK and PD properties. The number of conceivable structures are in billions rendering the breath of the

claims large.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the art of pharmaceutical chemistry, it is noted that each embodiment of the invention is required to be individually assessed for viability.

The amount of direction provided by the inventor and the presence or absence of working examples: The guidance and working examples provided in the specification are limited.

However, with respect to variables on the C linking biaryl unit (the term biaryl, as used herein refers to pyridine-benzene C of formula I, i.e., H) the disclosure in the specification is limited to one possibility, that is R3a = R2a' = R6a' = R2b = H and R6b = F. Enabling disclosure for no other possibility is present in the specification, because the Suzuki chemistry disclosed for making the unit is limited by the availability of the coupling partners with these substituents *as well as* the substituents A and B. While claimed many groups on the biaryl could be converted to the A and B fragments, it would require undue experiment for one skilled in the art.

Prior art teachings indicate that the aryl groups of the biaryl units remain rotatable independent of each other for retention of biological activity. There is nothing in the specification or in the prior art to indicate that atropisomerism is tolerated for retention of biological activity in this series of compounds. This is consistent with the enabled F substitution, given the similarity in atomic volume of F and H.

The possible variables on the biaryl are further limited by the lack of availability of substituted Suzuki coupling partners. The specification does not provide citations (commercial or literature) for procuring starting materials that could substitute for the lack of working examples for the undisclosed variables.

With respect to the variables A and B, the disclosure is enabling because of the prior art teachings of Lee et al. However, the language of 'independently' varying A and B, has no support in the specification. Thus, A is always linked to the phenyl portion and B is always linked to the 2-position of the pyridine of the biaryl. Thus the making and using aspect of the enablement excludes the 'independent'

variation of A and B.

The state and the predictability of the art: The state of the art is unpredictable as to functional group compatibility during many chemical transformations, in spite of major advances in protecting group strategies in synthesis. The biological activity present in the specification page 76 corresponds to phenyl-phenyl linkage for the C unit of the formula (I). Thus the specification is not enabling for the elected pyridine-benzene biaryl H for C of the formula (I). There is nothing in the specification showing that the generic statement found in lines 9 and 10 of page 76 pertains to the elected compounds. Such uncertainties and limitations establish that the contemporary knowledge in the art of medicinal chemistry would prevent one of ordinary skill in the art from accepting any claimed process described in the limited working examples on its face as universally applicable for making and using the compounds of formula I.

The quantity of experimentation: In the instant case, there is a substantial gap between the compounds demonstrated and the breadth of the claims. Lack of information regarding pharmacaphore and/or biological activity coupled with the plethora of structural possibilities claimed would necessitate a burdensome amount of research for one of ordinary skill in the art to identify embodiments that would have the desired biological activity.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

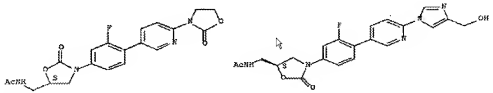
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

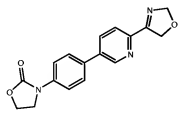
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-7, 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. WO 2001094342 Publication in English Date 12.13.2001.

Lee et al. teach oxazolidinones as antibacterial agents such as,



as two possibilities of many disclosed structures similar to compounds of the instant case shown below without the claimed substituents.



Lee et al. does not teach all the possible substituents claimed (but not enabled see rejection under 35 U.S.C. 112 first and second paragraph).

However, one of ordinary skill in the art would be motivated to make additional analogs of Lee et al. compounds, with substituents claimed in the instant case with reasonable to amount of success because such analog modifications are routine in the art of medicinal chemistry to optimize potency, PK and PD properties. The instantly claimed compounds would have suggested and thus obvious to one skilled in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-7, 9 and 14 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 11569150, 11569148, 11569408, 11569208, 10506020,10536687. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the all the applications are similar and are intended for the same utility.

It is noted that the applicant has additional applications reading on the claims of the instant case. Applicant should examine these and provide appropriate disclaimers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-7, 9 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 7192974. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds of the all the applications are similar and are intended for the same utility.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 3-7, 9 and 14 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim1-17 of prior U.S. Patent No. 7192974. This is a double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nizal S. Chandrakumar

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625